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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,640	02/19/2004	Taro Aoki	249160US0X	1883
22850	7590	10/21/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,640

Applicant(s)

AOKI ET AL.

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 6 is/are rejected.
- 7) ☒ Claim(s) 1,2 and 4-6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-6 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed May 25, 2004 have been received and entered into the application. Accordingly, the paragraph bridging pages 2-3 of the specification has been amended. Also, as reflected by the attached, completed copy of form PTO-1449 (1 page), the cited references have been considered.

Claim/Specification Objections

Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Throughout the specification and in claims 1, 2, 5 and 6, the term "pitavastatins" is objected to because pitavastatin is a particular chemical entity and it is improper to express this entity in the plural tense.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are indefinite because they omit an essential element from the claimed subject matter. In particular, claim 1 is directed to a composition having no ingredient amounts

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set forth ("an effective amount" would be sufficient to overcome this point of rejection). In claim 6, a host to whom the specified agents are administered is not set forth.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (Int. J. Clin Lab. Res. Reference cited by applicants) in view of applicants' acknowledgement at page 4, line 13 – page 5, line 1 of the specification and Fujikawa et al. (U.S. Patent No. 5,856,336, cited by applicants).

Nakamura et al. teach a combination of an HMG-CoA reductase inhibitor, such as pravastatin and eicosapentaenoic acid or its ethyl ester, as being effective for treating hyperlipidemia and shows that the combination effectively reduces plasma levels of total

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cholesterol and triglycerides (see the abstract, page 22, col. 2, third paragraph under "Introduction" and page 24, the entire section under "Discussion").

The difference between the above and the claimed subject matter lay in that Nakamura et al. fail to highlight the claimed pitavastatin compounds.

However, the difference between the subject matter sought to be patented and the prior art is such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because as acknowledged by applicants, the claimed pitavastatin compounds were known from among such references as Fujikawa et al. and Fujikawa et al. teach that the compounds are effective HMG-CoA reductase inhibitors (see, for example, the abstract). The skilled artisan would have been motivated to employ the claimed pitavastatin compounds in combination with eicosapentaenoic acid or its ethyl ester in the manner taught by Nakamura et al. because it is would have been clear from Nakamura et al. that HMG-CoA reductase inhibitors as a class would be useful and pitavastatin was known to belong to that class of inhibitors.

The data in the present specification at pages 8-10 have been considered, but fail to diminish the propriety of the present rejection because (a) the conclusion that the results are "synergistic" is not factually supported, (b) it has not been explained what the skilled artisan would have expected from such a combination and (c) the criticalness of using pitavastatin has not been demonstrated, i.e., it has not been established by any comparative data, i.e., the testing of different HMG-CoA reductase inhibitors, that the results obtained by Applicants are any different than what would have been expected given the teachings and data of Nakamura et al.


None of the claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

October 6, 2004